

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Pan et al.)	
Serial No.: 10/600,180)	
Filing Date: June 20, 2003)	Examiner: Necholas Ogden, Jr.
For: Antimicrobial Compositions,)	Group Art Unit No.: 1751
Products and Methods Employing)	Confirmation No.: 9698
Same)	

Second Declaration of Dr. Michael Lynch under 37 C.F.R. § 1.132

I, Dr. Michael Lynch, declare that:

1. I am President of Third Stream Bioscience, Inc., a licensee of the pending application.

2. I previously executed the declaration dated October 31, 2007 in this application.

3. I have read the Office Action dated January 8, 2008 in this application. In addition, I understand that the present declaration is submitted as evidence that the invention claimed in Appendix A is not obvious.

4. The invention of the present application is related to antimicrobial compositions, products and methods of using the same.

5. The antimicrobial compositions have a pH of from about 2.0 to about 4.5 and comprise three components:

- a. from about 0.2-70% organic acid (pyroglutamic acid or gluconic acid);
- b. a calcium ion scavenger (citric acid, malic acid, succinic acid, or polyacrylic acid);

- c. from about 0.1-40% of an anionic surfactant mixture having a characteristic selected from the group consisting of:
- a C₄₋₁₂ linear alkyl chain with a total hydrophilic head group size of at least about 4 Angstroms,
 - a C₄₋₁₂ unsaturated alkyl chain
 - a C₄₋₁₂ branched alkyl chain, and
 - combinations thereof.

6. During my review, I considered the knowledge of one of ordinary skill in the art including U.S. Pat. No. 6,190,675 (Beerse). In my opinion, Beerse does not teach or suggest the claimed compositions because Beerse does not teach the specific combinations of ingredients required by new claim 44.

7. My opinion is based on the following data from Table 4 which is described on page 23 of the specification and additional experiments carried out on antimicrobial compositions falling within the claims.

TABLE 4- EFFICACY OF COMPOSITIONS

Liquid Composition	E. coli Log reduction: 10% KJH (1 ml): solution at w/v%	E. coli Log Reduction: Immediate: Vitro skin	E. coli Log Reduction: Residual: Vitro skin	Rotavirus Log Reduction: Immediate: Vitro skin	Rotavirus Log Reduction: Residual: Bio skin
EX 1	5	4	4	3	
EX 3	5	5	5	3	3
EX 4		3	2		
EX 7		4	4		
EX 8		4	5		
EX 9		4	4		
EX 10		3	4		
EX 11	5	3	4	2	

The compositions of the examples are listed in Table 1 and reproduced below:

Component	EX 1	EX 2	EX 3	EX 4	EX 5	EX 6	EX 7	EX 8	EX 9	EX 10	EX 11	EX 12 (Cont)
Sodium Octyl Sulfate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	15
Sodium Salt Pyridinium Carboxylate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		0.5	
Glucosac Acid									1.5	1.5		15
Hydroxyethyl Cocaine Oil	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	1.0
Panthenol	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.5
Ascorbic Acid	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	1.0
Succinic Acid	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5				5
Malic Acid											1.5	
Mercuric Chloride		1.0										1.0
Nitro-Ethylbenzyl amyl 1,3 Propanediol			0.5									
Nonoxonyl Chloride				0.1								
Propylene Glycol					3							
2-Propanol						8						
Alc Vera							0.1					
Menthol								0.1				
PH adjusted by 1N NaOH	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

8. Table 1 provides Examples 1-8, 10-12, and 15 which are within the scope of the claims. Table 4 provides efficacy data for Examples 1, 3, 4, and 7-11. Additional compositions have been tested and achieve at least the results reported in Table 4. For example, compositions including succinic acid and pyroglutamic acid achieved comparable results to the Examples of Table 4.

9. As can be seen in the column titled, "E. coli Log Reduction Residual: Vitro skin", Examples 1, 3, 4, and 7-11 each show at least log 3 reduction of E. coli on Vitro skin after 15 minutes. This amount of antimicrobial efficacy is surprising for any antimicrobial composition. Moreover, it is surprising for a composition that does not rely on an antimicrobial active such as Triclosan or iodine.

10. The FDA has specific criteria for final formulations of health care personnel handwashes, surgical hand scrubs, and patient preoperative skin preparations. Log 3 reduction, representing a kill of about 99.9% of bacteria, is sufficient to establish effectiveness for each these indications. Not only do the Examples in Table 4 show log 3 reduction immediately, they maintain log 3 reduction even after 15 minutes on Vitro skin.

11. The results reported in Table 4 are representative of compositions within the scope of the new claims as presented in the attached Amendment.

12. In addition, Table, 3, below, shows the efficacy of Example 7.

EFFICACY OF COMPOSITIONS

Liquid Composition	Challenge Organism	Log reduction Time Kill (1 min): Suspension Test
EX 7	E. coli ATCC 11229	> 4
EX 7	Corynebacterium striatum ATCC 6940	> 4
EX 7	Corynebacterium mucifaciens axillary isolate 29	> 3
EX 7	Staphylococcus epidermidis ATCC 12228	3
EX 7	Staphylococcus epidermidis axillary isolate 9	> 4

Example 7 is shown to have greater than log 4 kill in 1 minute versus E. coli, corynebacterium stratus, and staphylococcus epidermis axillary isolate 9. Moreover, Example 7 has at least log 3 kill versus corynebacterium mucifaciens axillary isolate 29. Example 7 is within independent claim 44 and its efficacy against all of these organisms is unexpected. Moreover, the unexpected results of Example 7 are representative of the compositions now claimed in claim 44, and the unexpected results extend through the scope of the claims in the attached amendment.

13. The results reported above are statistically significant and scientifically meaningful.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Dr. Michael Lynch

SUBSCRIBED AND SWORN BEFORE ME
ON THIS 4 DAY OF April 2009
Nancy A. Steele
NOTARY PUBLIC

